

EXTRACT FROM PRODUCT INSERT

RESIST-3
O.K.N. K-SeT



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PERFORMANCE

A. Detection Limit

The detection limit determined with purified recombinant proteins of OXA-48, KPC and NDM have been evaluated at 0.125 ng/ml, 0.625 ng/ml and 0,25ng/ml respectively.

B. Validation on collection of reference strains

The RESIST-3 O.K.N. K-SeT test was evaluated on a collection of 200 clinical isolates with fully characterized resistance mechanisms to beta-lactams by phenotypic and molecular tests (France).

200 collection strains	27 strains tested positive for KPC with K-SeT test	27 strains carrying a KPC carbapenemase	<i>Escherichia coli</i> , <i>Klebsiella ozaenae</i> , <i>Enterobacter cloacae</i> , <i>Citrobacter freundii</i> , <i>Serratia marcescens</i> (positive for KPC-2 or KPC-3).
	30 strains tested positive for NDM with K-SeT test	30 strains carrying a NDM carbapenemase	<i>E. coli</i> , <i>K. pneumoniae</i> , <i>E. cloacae</i> , <i>Morganella morganii</i> , <i>Providencia spp.</i> , <i>Salmonella spp.</i> (positive for NDM-1, NDM-4,-5,-6,-7 or -9)
	43 strains tested positive for OXA-48 with K-SeT test	43 strains carrying a OXA-48 carbapenemase	<i>E. coli</i> , <i>E. cloacae</i> , <i>Enterobacter aerogenes</i> , <i>C. freundii</i> , <i>Citrobacter koseri</i> , <i>K. pneumoniae</i> (positive for OXA-48, -162, -181, -204, 232, -244)
	100 strains tested negative with K-SeT test	40 strains carrying a carbapenemase other than KPC, NDM or OXA-48 like	IMI-1/-2, Sme-1/-2, NmcA, GES-5, FRI-1, GIM-1, IMP-1,IMP-8, IMP-10, IMP-11 , VIM-1, VIM-2,-VIM-4, VIM-19
		60 strains not carrying a carbapenemase	

C. Prospective study

The RESIST-3 O.K.N. K-SeT kit was validated by comparison with reference molecular method (validated in house multiplex PCR including sequencing) in the National Reference Laboratory for Multidrug-Resistant Gram Negative Bacilli (Belgium) in a prospective study performed on 173 non duplicated, consecutive suspected CPE clinical isolates referred from July to September 2016.

OXA-48 status				
RESIST-3 O.K.N. K-SeT		Positive	Negative	Total
	Positive	69*	0	69
	Negative	0	104	104
	Total	69	104	173

95 % Confidence Interval ¹

Sensitivity:	100 %	(95.7 to 100 %)	Positive Predictive value:	100 %	(95.7 to 100 %)
Specificity:	100 %	(97.2 to 100 %)	Negative predictive value:	100 %	(97.2 to 100 %)
Agreement:	100 %	(173/173)			

KPC status				
RESIST-3 O.K.N. K-SeT		Positive	Negative	Total
	Positive	9	0	9
	Negative	0	164	164
	Total	9	164	173

95 % Confidence Interval ¹

Sensitivity:	100 %	(68.4 to 100 %)	Positive Predictive value:	100 %	(68.4 to 100 %)
Specificity:	100 %	(98.2 to 100 %)	Negative predictive value:	100 %	(98.2 to 100 %)
Agreement:	100 %	(173/173)			

NDM status				
RESIST-3 O.K.N. K-SeT		Positive	Negative	Total
	Positive	19*	0	19
	Negative	0	154	154
	Total	19	154	173

95 % Confidence Interval ¹

Sensitivity:	100 %	(84.7 to 100 %)	Positive Predictive value:	100 %	(84.7 to 100 %)
Specificity:	100 %	(98.1 to 100 %)	Negative predictive value:	100 %	(98.1 to 100 %)
Agreement:	100 %	(173/173)			

*: One OXA-48 + NDM isolate correctly detected by RESIST-3 O.K.N. K-SeT

A. Repeatability and reproducibility

To check intra-batch accuracy (repeatability), the same positive samples and a buffer solution were processed 15 times on kits of the same production batch in the same experimental conditions. All observed results were confirmed as expected.

¹ Newcombe, Robert G. "Two-Sided Confidence Intervals for the Single Proportion: Comparison of Seven Methods," *Statistics in Medicine*, 17, 857-872 (1998).